

### **REMARKS**

Claims 27-29 and 34 have been amended herein. Claim 33 has been cancelled herein. Claims 1-26 were cancelled in a Preliminary Amendment. Claims 35-41 have been withdrawn from consideration. Claims 27-32, 34, 42, and 43 are presented for the Examiner's review and consideration. Applicants believe that the claim amendments and accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

#### **Amendments to the Claims**

No new matter has been added by the amendments to claims 27-29 made herein. These claims were amended to clarify that the claimed peptides can be isolated or synthetic. This amendment is supported in the specification as originally filed, for example, in paragraph [0070] of the published application.

Additionally, claim 28 has been amended to delete the term "substantially" and the phrase "or functional analogues, derivatives or fragments thereof."

No new matter has been added by the amendments to claim 34 made herein. This claim was amended to clarify that the pharmaceutical composition can be used for inducing apoptosis in malignant cells. This amendment is supported in the specification as originally filed, for example, in paragraphs [0012]-[0016] and in Example 1, in which apoptosis induction in MeWo cells (melanoma cell line) is described.

Additionally, claim 34 has been amended to correct claim dependency in light of the claim cancellations.

#### **Rejection under 35 USC § 101**

Claims 27-29 were rejected under 35 USC § 101 because the claimed invention is allegedly directed to non-statutory subject matter. For reasons set forth below, Applicants respectfully submit that this rejection should be withdrawn.

The Examiner asserts that, as claimed, the peptides are products of nature which will occur in the apoptosis process.

As indicated above, claims 27-29 have been amended to clarify that the claimed peptides are isolated or synthetic. *See* paragraph [0070] of the published application. Thus, Applicants respectfully submit that claims 27-29, as amended herein, are drawn to patentable subject matter.

In light of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 27-29 under 35 USC § 101.

#### Rejections under 35 USC § 112

Claims 27, 28, and 30-34 were rejected under 35 USC § 112, first paragraph, as allegedly failing to comply with the written description requirement. For reasons set forth below, Applicants respectfully submit that this rejection should be withdrawn.

The Examiner states that the claims are drawn to a livin-derived peptide selected from one of p30-Livin  $\alpha$  and p28-Livin  $\beta$ , wherein said p30-Livin  $\alpha$  peptide comprises the sequence *substantially* as defined in SEQ ID NO:1, or *functional analogues, derivatives, or fragments thereof* having pro-apoptotic activity, and wherein said p28-Livin  $\beta$  peptide comprises the sequence *substantially* as defined in SEQ ID NO:2, or *functional analogues, derivatives, or fragments thereof* having pro-apoptotic activity and pharmaceutical compositions containing them. The Examiner concludes that, besides the specific peptides of p30-Livin  $\alpha$  and p28-Livin  $\beta$  which have adequate written description in terms that the structure and function is defined, the claims are drawn to a genus of peptides defined by functionality only. Emphasis added by the Examiner.

Without conceding to the Examiner's assertions, and in order to expedite prosecution, claim 28 has been amended herein to delete the term "substantially" and the phrase "or functional analogues, derivatives or fragments thereof."

In light of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 27, 28, and 30-34 under 35 USC § 112, first paragraph (written description).

Claims 27-34 were rejected under 35 USC § 112, first paragraph, because the specification, while being enabling for p30-Livin  $\alpha$  and p28-Livin  $\beta$  to induce apoptosis in certain cell lines when triggered by certain apoptosis inducing regimens, allegedly does not reasonably provide enablement for functional analogues, derivatives, or fragments of either p30-Livin  $\alpha$  or p28-Livin  $\beta$  to induce pro-apoptotic activity in all cells with any apoptotic trigger. For reasons set forth below, Applicants respectfully submit that this rejection should be withdrawn.

Without conceding to the Examiner's assertions, and in order to expedite prosecution, claim 28 has been amended herein to delete the phrase "or functional analogues, derivatives or fragments thereof."

In light of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 27-34 under 35 USC § 112, first paragraph (scope of enablement).

Claims 27-34 were rejected under 35 USC § 112, second paragraph, as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. For reasons set forth below, Applicants respectfully submit that this rejection should be withdrawn.

The Examiner states that since the functional analogues, derivatives, or fragments do not have an adequate written description, the metes and bounds of the claims can not be determined. The Examiner further states the term "substantially" is a relative term which renders the claims indefinite and it is unclear how the intended use limitations (claims 33, 34) would further limit the claimed composition.

Without conceding to the Examiner's assertions, and in order to expedite prosecution, the following amendments have been made: First, claim 28 has been amended to delete the term "substantially" and the phrase "or functional analogues, derivatives or fragments thereof." Claim 33 has been cancelled. And claim 34 has been amended to delete the phrase "programmed cell death of" and insert the phrase "apoptosis in." Thus, claim 34 further limits the composition by specifying that the apoptosis induced by the composition occurs in malignant cells.

In light of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 27-34 under 35 USC § 112, second paragraph.

Rejection under 35 USC § 102(a)

Claims 27-29, 42, and 43 were rejected under 35 USC § 102(a) as allegedly being anticipated by Nachmias et al. (Cancer Research 63: 6340-6349, October 1, 2003). For reasons set forth below, Applicants respectfully submit that this rejection should be withdrawn.

Applicants respectfully point out that the instant application claims priority to Israeli Patent Application No. 156263, which was filed on June 2, 2003. When viewing the information for the instant application in PAIR, the priority claim is clearly evident under the “foreign priority” tab. As noted above, the journal article by Nachmias et al. was published on October 1, 2003. Therefore, Nachmias was published after the date of priority and cannot be considered as prior art available at the time of filing of the instant application.

In light of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 27-29, 42, and 43 under 35 USC § 102(a).

Rejection under 35 USC § 103(a)

Claims 30-34 were rejected under 35 USC § 103(a) as allegedly being unpatentable over Nachmias et al. (Cancer Research 63: 6340-6349, October 1, 2003) in view of information allegedly well-known in the art at the time that the invention was made (formulation of a pharmaceutical composition and use of viral vectors). Specifically, the Examiner asserts that it would have been obvious for a person of ordinary skill in the art at the time that the invention was made to use the core teachings of Nachmias et al. to design a pharmaceutical formulation with a reasonable expectation of success, due to the high level of skill in the art. The Examiner further asserts that the motivation to do so is offered by Nachmias et al. which suggests using the peptides for treatment of drug resistant malignant melanomas.

As established above, Nachmias was published after the date of priority, and therefore cannot be considered as prior art available at the time that the invention was made.

In light of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 30-34 under 35 USC § 103(a).

**Conclusion**

In light of the foregoing amendments and remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this response or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

The fee for submission of an information disclosure statement pursuant to Section 1.17(p) in the amount of \$180 is believed to be due and is being paid by credit card. No other fee is believed to be due. However, please charge any other required fee (or credit overpayments) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 7640-X05-046).

Respectfully submitted,

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